510(k) Summary
EndoChoice Hot Biopsy Forceps

1. Company Identification

EndoChoice, Inc.
11800 Wills Road, Suite 100
Alpharetta, GA 30009
Telephone
Fax (678) 567 8218
Establishment Registration: 300759133

OCT 15 2013

2. Contact Person

Daniel Hoefer
Regulatory Affairs Manager

3. Device Name

Commercial name: *EndoChoice Hot Biopsy Forceps*
Classification name: Forceps, Biopsy, Electric

4. Device Classification

Product Code: KGE
Regulation Number: 876.4300
Class: II

5. Intended Use

EndoChoice Hot Biopsy Forceps are intended for use by trained medical professionals. The device is to be used endoscopically in conjunction with monopolar electrosurgical current to obtain gastrointestinal mucosal tissue biopsies and for removal of sessile polyps.

6. Device Description

EndoChoice Hot Biopsy Forceps is a sterile single use device designed for use in the gastrointestinal tract. A plug is located on the handle for connection to an electrosurgical unit, giving the capability to apply high frequency monopolar electrocautery during resection.

The device is compatible with endoscopic access channels of at least 2.8 mm and is provided with a working length of 230.0 cm.

Using the EndoChoice Hot Biopsy Forceps, the user can cauterize and remove tissue from the mucosal wall by using the handle to open the jaws, pressing the jaws against the site, closing, applying electrical current via a compatible electrosurgical unit (not included), and gently pulling the away from the site.

7. Substantial Equivalence

The EndoChoice Hot Biopsy Forceps is substantially equivalent to the Radial Jaw 4™ Hot Biopsy Forceps (K101657) manufactured by Boston Scientific Corporation.

The devices are equivalent in terms of intended use, operating principle, technology, energy used, packaging, and materials.

8. Non-Clinical testing

Testing includes:

- Bench testing of the functional performance,
- biocompatibility testing,
- sterility assurance validation,
- shelf life testing,
- electrical safety testing for high frequency surgical accessories.

Results demonstrate that the device is safe and effective in meeting user requirements in accordance with its intended use.

9. Conclusion

The EndoChoice Hot Biopsy Forceps is substantially equivalent to the predicate device listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 15, 2013

EndoChoice, Inc.
% Daniel Hoefer
Regulatory Affairs Manager
11810 Wills Road
Alpharetta, GA 30009

Re: K131991
Trade/Device Name: EndoChoice Hot Biopsy Forceps
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KGE
Dated: August 19, 2013
Received: August 20, 2013

Dear Daniel Hoefer,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131991

Device Name: EndoChoice Hot Biopsy Forceps

Indications for Use:

EndoChoice Hot Biopsy forceps are indicated for endoscopic use in in conjunction with monopolar electrosurgical current to obtain gastrointestinal mucosal tissue biopsies and for removal of sessile polyps.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Benjamin R. Fisher -S
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